REMARKS

Entry of the foregoing, reexamination and reconsideration of the subject application are respectfully requested in light of the amendments above and the comments which follow.

As correctly noted in the Office Action summary, claims 1-16 and 52-66 were pending. By the present response, claims 1, 52 and 60 have been amended, and claims 67-68 have been added. Therefore, upon entry of the present response, claims 1-16 and 52-68 are pending await further consideration on the merits.

OBJECTION TO THE SPECIFICATION

The title objected to on the grounds set forth on page 2 of the Official Action. By the present response, the title has been amended in a manner which is believed to address the objection. Therefore, reconsideration and withdrawal of the objection is respectfully requested.

CLAIM REJECTIONS UNDER 35 U.S.C. §112

Claims 60-66 stand rejected under 35 U.S.C. §112, first paragraph as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. In particular, it is asserted that:

> The claimed coating comprises a conducting coating which is not disclosed in the specification (the specification disclose only a non-conducting, morphology-improving coating). Therefore, the claimed coating is new matter, because it comprises material which is not included in the original specification.

This rejection is traversed.

With regard to the claimed coating, it is disclosed, for example, that:

> Preferably, the non-conductive surface comprises a non-conductive coating affixed to one side of a flexible substrate . . . (page 5, lines 22-23); and

> The purpose of this coating is to provide a non-conductive barrier between the base material and the conductive layer and to improve the flatness of the surface morphology of the non-conductive surface . . . (page 5, lines 30-page 6 line 1).

As illustrated by the above, the "surface morphology-improving coating" recited in claim 60 is clearly adequately supported by the original disclosure.

Nothing in 35 U.S.C. §112 requires the claims to correspond to the specific embodiments described in the specification. As a general rule, claims can cover more than the specific embodiments illustrated in the disclosure, if the prior art permits. In re Newton, 414 F.2d 1400, 1406, 163 USPQ 34, 39 (CCPA 1969). Therefore, 35 U.S.C. §112, first paragraph is still satisfied even the claims cover more than the preferred embodiments expressly described in the specification. In re Smythe, 480 F.2d 1376, 178 USPQ 279, 284 (CCPA 1973).

The rejection is not supported by either the facts or the law. For at least the reasons noted above, the rejection is improper and should be withdrawn.

Claims 52-66 stand rejected under 35 U.S.C. §112, second paragraph on the grounds set forth on page 3 of the Official Action. In particular, claims 52 and 60 stand rejected on the grounds that these claims are:

> Incomplete for omitting essential elements, such omission amounting to a gap between the elements. See, MPEP §2172.01. The omitted element is a reagent capable of reacting with the analyte in the fluid sample to produce a measurable electrical change.

Nothing in 35 U.S.C. §112, second paragraph requires a patent applicant to assert every conceivable feature associated with an invention set forth in the specification within the claims in order to satisfy the definiteness requirements of the statute.

The claim language is not required to enable one of ordinary skill in the art to make and use the invention, or satisfy the written description requirement, in order to satisfy the definiteness requirements of 35 U.S.C. §112, second paragraph, Rather, this is the purpose of the specification. In this regard, the Federal Circuit has held that:

> [I]t is entirely consistent with the claim definiteness requirements of the second ¶ of §112, to present "sub-combination" claims, drawn to only one aspect or combination of elements of an invention . . . Karl Zeiss Stiftung v. Renishaw PLC, 945 F.2d 1173, 20 USPQ2d 1094 (Fed. Cir. 1991).

Further, in this regard, the Federal Circuit has rejected arguments that claims are indefinite under 35 U.S.C. second paragraph because they did not describe a "workable invention". Miles Laboratories, Inc. v. Shandon, Inc., 997 F.2d 870, 27 USPQ2d 1123 (Fed. Cir. 1993, cert. denied, 510 U.S. 1100 (1994) (The above argument "is irrelevant to

definiteness under §112, ¶2. The invention's operability may say nothing about a skilled artisans understanding of the bounds of the claim.")

For at least the reasons noted above, the rejection is improper and should be withdrawn.

CLAIM REJECTIONS UNDER 35 U.S.C. §103(a)

Claims 1-16 and 52-66 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,437,999 to Diebold et al. (hereafter *"Diebold et al."*) in view of U.S. Patent No. 4,217,374 to Ovshinsky et al. (hereafter *"Ovshinsky et al."*) on the grounds set forth on page four of the Official Action. For at least the reasons noted below, the rejection should be withdrawn.

The present invention is directed to a test device The advantages of the present invention over conventional test devices are discussed in previous responses.

A device instructed according to the principles of the present invention is embodied in claim 1. Such a device includes:

> *(a) a single substrate, the single substrate comprising a non-conductive coating affixed to one side of a flexible material;*
> *(b) a working electrode comprising an amorphous semiconductor material affixed to the non-conductive coating, said working electrode having a first electrode area, a first lead and a first contact pad;*
> *(c) a counter electrode comprising an amorphous semiconductor material affixed to the non-conductive coating, said counter electrode having a second electrode area, a second lead and a second contact pad; and*
> *(d) a reagent capable of reacting with the analyte to produce a measurable change in potential which can be correlated to the presence or*

concentration of the analyte in the fluid sample, said reagent overlaying at least a portion of the first electrode area of the working electrode.

A device constructed according to a further aspect of the present invention is embodied, for example, in claim 52. Such a device includes:

a single substrate, the single substrate being of sufficient flexibility to undergo roll-type processing, the single substrate comprising a flexible metallic material;
a non-conductive, surface morphology-improving coating affixed to a surface of the single substrate; and
an amorphous semiconductor material layer affixed to the non-conductive coating.

A device constructed according to a yet another aspect of the present invention is embodied, for example, in claim 60. Such a device includes:

a single substrate, the single substrate being of sufficient flexibility to undergo roll-type processing, the single substrate comprising an annealed, preshrunk polymeric material;
a surface morphology-improving coating affixed to a surface of the single substrate; and
an amorphous semiconductor material affixed to the coating.

It is asserted in the Official Action that *Diebold et al.* discloses all features recited in the above-mentioned claims, except for the recited amorphous semiconductor material. This assertion, especially as it would be applied to amended claims 1, 52 and 60, is traversed.

It is asserted on page 4 of the Official Action that *Diebold et al.* discloses disposing an electric conducting material on a thin substrate which can be polyamide or another polymer. Column 3, lines 55-56; column 5, lines 66-67; and column 6, lines 35-60 are cited in support of the above assertion. In column 3 of *Diebold et al.*, in connection with

reference to Figure 1, there is described a thin support material 2 upon which an electrically conducting material 1 is vacuum sputtered or evaporatibly deposited. The combination of support material and electrically conducting material 1 forms a "metallized thin support material 3." However, the described embodiment further includes a "first insulating substrate 4" which has "the desired supportive rigidity." (See, e.g.-column 4, lines 23-32). The metallized thin support material 3 is laminated to the first insulating substrate 4. (See, e.g.-column 4, lines 23-25.) Therefore, it is clear that the device described in connection with the description appearing in columns 3 and 4 includes laminated multiple support members (e.g.-support material 2 and insulating substrate 4) which are taught as being combined to form a relatively rigid construction and which are not capable of being roll-processed. Such a construction is expressly contrary to the purpose and construction of the present invention. For example, amended claims 1, 52 and 60 all require that the device comprise a single substrate of flexible material. Therefore, *Diebold et al.* clearly fails to disclose, or even suggest at least this aspect of amended claims 1, 52 and 60.

It is further noted that column 5, lines 66-67 and column 6, lines 35-60 are referenced in connection with the thin substrate being formed of polyamide or other polymers. However, the embodiment described in column 5 and 6 of *Diebold et al.* is clearly distinguishable from the construction recited in amended claims 1, 52 and 60. First, the embodiment described in columns 5 and 6 clearly instructs the deposition of an electrically conducting material directly onto to the substrate surface, "thus facilitating a

less-expensive, semicontinuous production method." (See, e.g.-column 5, lines 59-61.) By contrast, claims 1, 52 and 60 require that the electrically conducting material be deposited, not directly upon the substrate, but upon an intervening coating. Secondly, the embodiment described in columns 5 and 6 also includes a "first insulating substrate 13" in addition to a "second insulating substrate 14." (See, e.g.-column 5, line 64 and column 6, line 17.) Therefore, the device described in columns 5 and 6 of *Diebold et al.* does not include a single substrate as required by amended claims 1, 52 and 60.

It is further asserted on page 4 of the Official Action, that *Diebold et al.* discloses a thin anchor layer deposited on the substrate to increase adhesion between the electrical conducting material and the thin substrate. Column 3, lines 58-65 are cited in support of the above assertion. *Diebold et al.* discloses an optional thin anchor layer of "chromium, titanium, or other suitable material (not shown in Fig. 1)." However, it is at best, unclear as to whether the described thin anchor layer satisfies the requirements that the coating be "non-conductive" or "surface morphology-improving" as required by amended claims 1, 52 and 60.

Claim 52 also requires that the single substrate as comprising "a flexible metallic material." *Diebold et al.* also fails to disclose at least this additional aspect of claim 52.

Claim 60 further recites the single substrate as comprising "an annealed, preshrunk polymeric material." *Diebold et al.* also fails to disclose at least this additional aspect of claim 60.

Therefore, for at least the reasons noted above, *Diebold et al.* fails to disclose or suggest the invention as recited by claims 1, 52 and 60

Ovshinsky et al. is applied as teaching use of an amorphous semiconductor material. However, *Ovshinsky et al.* does nothing to cure the above-noted deficiencies noted in connection with *Diebold et al.* Moreover, even if the teachings of *Ovshinsky et al.* were applied, one of ordinary skill in the art would have been led even further away from the presently claimed invention.

It is important to keep in mind that the teachings of prior art references must be considered as a whole. It is clearly improper to pick and choose from among the various teachings contained in the prior art reference, using applicant's own disclosure as a roadmap, in an attempt to reconstruct the prior art to meet the requirements of a claimed invention.

Ovshinsky et al. teaches the development of a semiconductor film for such applications as the construction of **solar cells**, not electrochemical test devices. Therefore, one of ordinary skill in the art would not have turned to *Ovshinsky et al.* in an attempt to modify the teachings of *Diebold et al.*

Moreover, *Ovshinsky et al.* clearly teaches application of an amorphous semiconductor material to a conductive surface, and not to a non-conductive coating as required by claims 1, 52 and 60. Therefore, even if one of ordinary skill in the art were to apply *Ovshinsky et al.*, an objective application of the teachings of the reference would

have taught away from the claimed amorphous semiconductor material applied to a non-conductive coating.

For at least the reasons noted above, the rejection is improper and should be withdrawn.

The remaining claims not expressly mentioned above depend either directly or indirectly upon claims 1, 52 or 60. Thus, these claims are also distinguishable over the applied prior art references for at least the same reasons noted above.

CONCLUSION

From the foregoing, further and favorable action in the form of a Notice of Allowance is earnestly solicited. Should the Examiner feel that any issues remain, it is requested that the undersigned by contacted so that any such issues may be adequately addressed and prosecution of the instant application expedited.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

By: _____
Scott W. Cummings
Registration No. 41,567

P.O. Box 1404
Alexandria, Virginia 22313-1404
(703) 836-6620

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